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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,368	12/12/2003	Craig A. Rosen	PZ045P1D1	2585

22195 7590 11/16/2006

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,368	ROSEN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-50* is/are pending in the application.

4a) Of the above claim(s) *49 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 8/31/06, is acknowledged.

3. Claims 25-50 are pending.

4. Claims 49-50 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

5. Claims 25-48 are under consideration in the instant application.

6. In view of the amendment filed on 8/31/06, only the following rejections are remained.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

8. Claims 25-48 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence for the claimed antibody or fragment thereof that specifically binds to a protein selected from the group consisting of: a) amino acids 34 to 766 of SEQ ID No: 35; b) amino acids 1 to 766 of SEQ ID No: 35; c) a mature portion of the HCE3C63 protein encoded by the HCE3C63 cDNA contained in ATCC Deposit No. PTA-909; and d) the full length HCE3C63 protein encoded by the HCE3C63 cDNA contained in ATCC Deposit No. PTA-909; wherein said antibody or fragment thereof is useful for detecting or treating any cancer for the same reasons set forth in the previous Office Action mailed 5/31/06.

Applicant's arguments, filed 8/31/06, have been fully considered, but have not been found convincing.

Applicant points out that the specification describes the invention as "useful for treatment, detection, diagnosis and/or prevention of cancer, particularly brain, bladder, ovarian, or skin cancer, squamous carcinoma, renal cell carcinoma or squamous cell oesophageal carcinoma. Applicant contends that one of skill in the art would understand that the claimed antibody is useful for treatment or diagnosis of the cancers and hyperporliferative disorders disclosed in the specification.

However, such use was based on the translation product homology of SEQ ID NO: 35 to the DBCCR1 and IB3089A tumor suppressor genes (see page 11, ¶32). Applicants based their original assumption on similarity to other proteins. The specification fails to disclose how the skilled in the art would be able to detect or treat a cancer. Since the specification fails to demonstrate "a differential expression" in both normal and a cancerous disease, methods of identifying or immunotherapeutic regiments is not substantiated. Is HCE3C63 product elevated or decreased in the cancer? Is HCE3C63 gene is deleted or overexpressed in the cancer. Further, Given that the art establish that DBCCR1 and IB3089A genes are deleted in the bladder cancer, it cannot be seen how the claimed antibodies would be use to treat none existent target in the cancer (based on original assumption on similarity). In the absence of any disclosed relationship between the polypeptide which the claimed antibody binds and any cancer and the lack of any correlation between the polypeptide which the claimed antibody binds and any cancer, the skilled in the art does not know how to use the anti-HCE3C63 antibodies to detect or treat cancer? The skilled in the art would not know how the claimed antibody would restore the loss of function of a deleted gene product (based on the original assumption). "The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements...However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims." MPEP § 2164.03. If the use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more complete statement of how to use must be supplied.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

10. Claims 25-33, 35-44 and 46-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EMBL accession number AL035289 (Rhodes, Jan- 1999) in view of Campbell (ed.), Monoclonal Antibody Technology, 1985; 2nd Edition as evidenced by Bost et. al. (Immunological Investigations, 1988; 17: 577-586) for the same reasons set forth in the previous Office Action mailed 5/31/06.

Applicant's arguments, filed 8/31/06, have been fully considered, but have not been found convincing.

Applicant argues that the claims now recite a functional parameter that is the antibodies are useful for detecting or treating cancer.

However, the resultant antibody would be expected to have the same functional activity as the claimed antibodies in the absence of evidence to the contrary.

11. Claims 25-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EMBL accession number AL035289 (Rhodes, Jan-1999) in view of Campbell (ed.), Monoclonal Antibody Technology, 1985; 2nd Edition, as evidenced by Bost et. al. (Immunological Investigations, 1988; 17: 577-586) as applied to claims 25-33, 35-44 and 46-48 above, and in further view of Owens et. al. (Journal of Immunological Methods. 1994; 168: 149-165 for the same reasons set forth in the previous Office Action mailed 5/31/06.

Applicant's arguments, filed 8/31/06, have been fully considered, but have not been found convincing.

Applicant argues that Owens et al do not disclose the present invention and therefore there would be no motivation or suggestion to use their teachings, alone or in combination with any other reference, to obtain the present invention. Further, Applicant argues that EMBL accession number ALO35289 discloses a single, partial sequence encoding a hypothetical protein wherein no polypeptide function or activity is disclosed or suggested. The fact that "antibodies are powerful immunochemical tools," would not motivate one of skill in the art to place the partial cDNA into an expression vector, transfect the partial cDNA in a suitable host cell, purify the partial polypeptide, generate antibodies from a partial polypeptide, and then screen the generated antibodies for use in diagnosing or treating cancer. Applicant contends that it is unlikely that one of skill in the art would be motivated to pursue a research plan ranging from several months to years based on the disclosure of a partial, hypothetical protein where no function or activity is disclosed or suggested solely because antibodies are powerful therapeutic tools.

However, expression of EST polypeptide or portions thereof, is useful because these gene products can be used as antigens to produce antibodies that can be used, for example, to screen cDNA expression libraries. Knowledge of the human EST cDNA sequence leads to knowledge of the EST protein sequence, which in turn makes possible the production of antibodies against portions of the protein sequence specific to human EST protein. Western blot analysis utilizing such antibodies are used to provide highly specific assays for human EST protein expression. Further, such antibodies can be used in order to identify the tissue type or cell species from which a sample is derived.

Applicant further argues that the skilled artisan would have no reasonable expectation of success using the single, partial sequence encoding a hypothetical protein disclosed EMBL accession number AL035289 in generating antibodies useful for diagnosing or treating cancer. Applicant argues that the combination of EMBL accession number AL035289 and of Campell, Bost et al and Owens et al does not teach or suggest any, much less all, the present functional parameters of the invention.

However, the resultant antibody from the combined reference teachings would be expected to have the claimed functional activity in the absence of evidence to the contrary.

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 2, 2006

Maher Haddad

Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600